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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,641	08/30/2001	Yasushi Sato	0263-4051	9688

7590

06/24/2004

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New York, NY 10154

EXAMINER

KEMMERER, ELIZABETH

ART UNIT PAPER NUMBER

1646

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/914,641

### Applicant(s)

SATO, YASUSHI

### Examiner

Elizabeth C. Kemmerer, Ph.D.

### Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-20 is/are allowed.
- 6) ☒ Claim(s) 21-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of Application, Amendments, And/Or Claims***

An amendment was received 26 March 2004 and has been entered in full.

Claims 27-30 are canceled. Claims 1-26 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Withdrawn Objections And/Or Rejections***

The rejection of claims 1-30 under 35 U.S.C. § 112, second paragraph, as set forth at pp. 2-3 of the previous Office Action (mailed 26 September 2003) is *withdrawn* in view of the amended and canceled claims (amendment received 26 March 2004).

The rejection of claims 1-4 and 6-18 under 35 U.S.C. § 102(b), as being anticipated by WO 94/14465 as set forth at p. 3 of the previous Office Action (mailed 26 September 2003) is *withdrawn* in view of the amended and canceled claims (amendment received 26 March 2004).

The rejection of claims 19-30 under 35 U.S.C. § 102(b), as being anticipated by JP 146829 as set forth at p. 4 of the previous Office Action (mailed 26 September 2003) is *withdrawn* in view of the amended and canceled claims (amendment received 26 March 2004).

The rejection of claim 5 under 35 U.S.C. § 103(a), as being unpatentable over WO 94/14465 in view of JP 63-146829 as set forth at pp. 4-5 of the previous

Office Action (mailed 26 September 2003) is *withdrawn* in view of the amended and canceled claims (amendment received 26 March 2004).

**35 U.S.C. § 103**

Claims 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (U.S. Patent 6,525,102 B1, issued 2/25/2003, effective filing date 10/4/1999) in view of Nabuchi et al. (1998, *Analytica Chimica Acta* 365:301-307).

Chen et al. teach a method for inhibiting a physiologically active protein containing a methionine residue from producing a variant oxidized at the methionine residue, comprising adding methionine to a composition containing said protein. See col. 10, li. 26-58; col. 30 li. 52 to col. 31, li. 46. Chen et al. teach the method wherein other proteins are not present as stabilizers (*ibid.*). Chen et al. teach the method wherein the composition is in the form of a solution (*ibid.*). Chen et al. teach a stabilized composition comprising the protein and methionine and arginine, which is substantially free from other proteins as stabilizers (*ibid.*).

Chen et al. do not teach the methods and compositions wherein the protein is PTH. However, Chen et al. suggest using the method and making similar compositions using other proteins susceptible to degradation (col. 12, li. 21-38). The degradation discussed by Chen et al. involves oxidation of methionine residues within the protein (col. 10, li. 26-58). Nabuchi et al. teach that PTH has two methionine residues that are susceptible to oxidation, leading

to degradation and loss of biological activities (pp. 301-302, introduction).

Nabuchi et al. state that this chemical degradation via oxidation is critical in optimizing medical formulations (ibid.).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the methods and compositions of Chen et al. by substituting the PTH of Nabuchi et al. with a reasonable expectation of success. the motivation to do so could be found in Nabuchi et al.'s comments regarding the desirability of improving the stability of medical formulations of PTH by minimizing degradation via methionine oxidation, and Chen et al.'s suggestion that active proteins comprising methionine residues susceptible to oxidation can be stabilized by formulation with methionine and arginine.

Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

### **Conclusion**

Claims 1-20 are allowable. Claims 21-26 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is

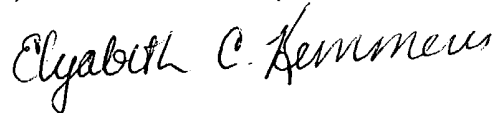
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filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Thursday, 7:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ECK

ELIZABETH KEMMERER  
PRIMARY EXAMINER